Remarks

Further and favorable reconsideration is respectfully requested in view of the foregoing amendments and following remarks.

Thus, claim 24 has been amended to delete reference to nicotine, thus now referring to nicotine salts.

Claim 28 has also been amended to require that the nicotine is present in the form of a salt. Accordingly, claim 30, which is directed to this embodiment now incorporated into claim 28, has been cancelled.

Claims 33 and 54 have been amended to change "water-soluble polymer" to --polyvinyl pyrrolidone and hydroxypropylmethyl cellulose-- considering the language employed in claim 28, on which claim 33 depends. These amendments are being made in response to the rejection of claims 33 and 54 under the second paragraph of 35 U.S.C. §112. In view of these amendments, the rejection has been rendered moot.

Other changes of a minor nature have been made in claims 33 and 54, to render them consistent with the use of "%-wt." in claims such as claim 35.

Claim 52 has been amended to depend on claim 28, in view of the cancellation of claim 30.

New claims 57-61 have been added to the application.

Claim 57 is supported by the disclosure in the paragraph bridging pages 5 and 6 of the specification.

Claim 58 is supported by the second paragraph on page 4, together with Example 2. Applicants note that the Kollidon referred to in Example 2 is polyvinyl pyrrolidone.

Claim 59 is supported by Example 5.

Claims 60 and 61 correspond to claim 52 except for their dependency.

The patentability of the presently claimed invention over the disclosures of the references relied upon by the Examiner in rejecting the claims will be apparent upon consideration of the following remarks.

Thus, the rejection of claims 24-29, 31, 33-36, 38-40 and 53-56 under 35 U.S.C. §103(a) as being unpatentable over Majeti (US '554) is respectfully traversed.

Applicants respectfully submit that this rejection has been rendered moot in view of the claim amendments. That is, claim 28 has been amended to incorporate the subject matter of

claim 30 (dependent on claim 28), which is not subject to this rejection. Similarly, like claim 28, the only other independent claim subject to this rejection, i.e. claim 24, has also been amended to limit the pharmaceutically active agents to nicotine salts.

The rejection of claims 10-23 and 37 under 35 U.S.C. §103(a) as being unpatentable over Majeti in view of Story et al. (US '949) is respectfully traversed.

Initially, claim 37 is dependent on claim 28, which was among the claims rejected based only on the Majeti reference. As indicated above, the rejection of this claim based on Majeti has been rendered moot. For this reason alone, the rejection based on a combination of Majeti with Story et al. should also be withdrawn.

The Examiner acknowledges that the Majeti reference differs from the instant claims insofar as it does not disclose compositions comprising a mixed surfactant system comprising polyoxyethylene sorbitan fatty acid ester or alpha-hydroxy-omega-hydroxypoly(oxyethylene)-poly(oxypropylene)poly(oxyethylene) block copolymer, and polyoxyethylene alkyl ether or a polyoxyethylene castor oil derivative (component v of claim 10, the only independent claim subject to this rejection). The Examiner then takes the position that Story et al. suggest using a mixture of surfactants as recited in present claim 10 (and 37).

However, Applicants disagree with this view since, contrary to the Examiner's statement, Story et al. cannot be regarded as a "general teaching" on surfactants. Rather, this prior art teaches how a specific class of drug substances (NSAIDs) can be formulated to give micelle-forming compositions by using certain types of surfactants (column 4, lines 33-54). According to Story et al., micelle formation was considered necessary to protect the gastrointestinal tract from harmful side-effects caused by NSAIDs (column 4, lines 8-10 and 28-38).

Since the composition of present claim 10 adheres to the oral cavity and effects the transmucosal delivery of the active substances released therefrom, there is no need for protecting the gastrointestinal tract from the active ingredients, since they are already absorbed via the oral mucosa. The same applies with respect to the "transmucosally administrable compositions" disclosed by Majeti. Therefore, there was no motivation for combining Story et al. with Majeti. According to the present invention, the use of a specific combination of surfactants (as defined in claim 10) resulted in mucoadhesive compositions having instant wettability (see the present published application, US 2004/0156885 A1, paragraphs [0011-0013]. The prior art failed to

suggest that the wettability of mucoadhesive films could be improved by using a mixture of surfactants, let alone a mixture of surfactants as presently claimed.

With respect to new claim 57, it is noted that this claim recites various classes of pharmaceutically active ingredients, without including NSAIDs that are taught by Story et al. Since this prior art teaching concerns micelles formed by combining NSAIDs with certain surfactants, the skilled person would not have considered this teaching in the case where different types of active substances are used (e. g. pharmaceutically active agents as recited in claim 57).

On page 7, lines 11-14 of the Office Action, the Examiner suggests that it "would have been obvious ... to have used the surfactants and mixtures thereof in the compositions of the primary reference motivated by the desire to ensure the ... active agent was thoroughly dissolved and made a uniform mixture throughout the film as taught by Story et al." This suggestion, however, cannot be derived from Story et al.'s teaching, since this prior art merely teaches that certain surfactants may be suitable to form micelles when combined with NSAIDs, in order to protect the gastrointestinal tract from these drugs. Further, Story et al. fail to teach or suggest that the micelles described in this reference could be "made a uniform mixture throughout the film" as suggested by the Examiner, since Story et al. do not consider films at all. Hence, the art-skilled would doubt that it is feasible to incorporate micelles into a film that is applicable to the oral mucosa, and it also questionable whether the micelles taught by Story et al. could be uniformly distributed within a mucoadhesive film.

The above arguments also apply with respect to new dependent claim 58. In addition, it is submitted that the prior art fails to suggest using a mixture of polyvinylpyrrolidone, polyethylene glycol and hydroxypropylmethyl cellulose, as defined in claim 58, in the mucoadhesive layer as defined in claim 10.

The rejection of claims 30 and 52 under 35 U.S.C. §103(a) as being unpatentable over Majeti in view of Stanley et al. (US '207) is respectfully traversed.

The limitation – nicotine salts – formerly contained in claim 30 is now incorporated in amended claim 28. In this connection, the Examiner has referred to Stanley et al. for disclosing dosage forms comprising nicotine and its salts. However, the primary reference (Majeti) teaches the combined administration (transdermal or transmucosal) of nicotine and caffeine.

As stated by Stanley et al. (column 7, lines 38-44), and as acknowledged by the Examiner, nicotine salts are not readily absorbable through mucosal membranes. Since, according to Majeti, it is important that the two active components – nicotine and caffeine – are co-administered (see column 1, line 66, to column 2, line 12), the skilled person would not have considered replacing nicotine with a salt thereof, as he/she would have assumed that this salt would be absorbed only at insufficient rates, in relationship to caffeine which is co-administered. Also, at the time when Majeti's invention was made, nicotine salts were already well known in the art.

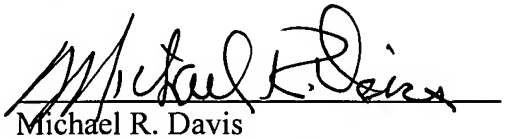
Therefore, the fact that Majeti fails to include "nicotine salts" indicates that such salts were not considered suitable for use in this invention (note that Majeti mentions "caffeine or caffeine equivalent", but does not recite "nicotine or nicotine equivalent"). Applicants submit that the skilled person would not have considered the possibility of replacing nicotine with nicotine salts in the invention described by Majeti.

For these reasons, Applicants take the position that the presently claimed invention is clearly patentable over the references applied by the Examiner in rejecting the claims.

Therefore, in view of the foregoing amendments and remarks, it is submitted that each of the grounds of rejection set forth by the Examiner has been overcome, and that the application is in condition for allowance. Such allowance is solicited.

Respectfully submitted,

Horst Georg ZERBE et al.

By: 

Michael R. Davis
Registration No. 25,134
Attorney for Applicants

MRD/pth
Washington, D.C. 20006-1021
Telephone (202) 721-8200
Facsimile (202) 721-8250
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